

microarterial allografts and autografts in rats. Pratt stated that freeze-drying only retarded the process the post immune reaction, but seem to prevent immune response to the allografts in the study. It should be noted that Pratt's conclusion is that freeze-dried microarterial allografts are reliable vascular substitutes, but maintain patentcy for a period of only as long as two months. Page 704 of the Chow reference states that the patency rate of freeze-dried grafts was as high as 85 percent at two weeks but dropped dramatically to 55 percent in three months. Thus, Chow agrees with the Pratt references in that with freeze-dried grafts the absence of an immune response is only temporary. Chow also stated that more than 60 percent of the patent grafts showed dilation with occasional aneurysm formation. Also, most of the blocked grafts disintegrated at three months due to fibrosis. Thus, the Examiner's position that Pratt and Chow show that freeze-dried tissues prevent immune response is not completely accurate, since the freeze-dried vessels deteriorated markedly after a short period of time, i.e. two or three months.

Dardik et al teaches the employment of vessels from the umbilical cord for use in a tubular prosthesis during vascular reconstructive surgery. Dardik radically modified the vessels which not only destroyed patency, but caused an immune response. For example, Dardik shaped the vessel with a mandrel and soaked the same in glutaraldehyde solution. This caused hardening in the vessel into a rigid member. Following this tanning or denaturing

procedure, a polyester mesh was applied to the graft to add support. Thus, the Dardik graft vessel was rigid and non-elastic, unlike that claimed by Applicant.

The combination of Dardik and Pratt would suggest the processing of the Pratt and Chow vessels to treat them with tanning materials to prevent the lack of patency described in the Chow reference. Dardik makes no suggestion that vessels derive from the placental and/or umbilical tissue would be freeze-dried to yield a reconstructive allograft that exhibits low immune response over an extended period of time. In the alternative applying the teachings of the Pratt's references to Dardik would not lead one to proceed in this direction with any anticipation of success since the Pratt references admits that the patency and lack of immune response spans a very short period of time. The result would hardly suffice as an allograft in a human if failure of the allograft would occur in two months or less.

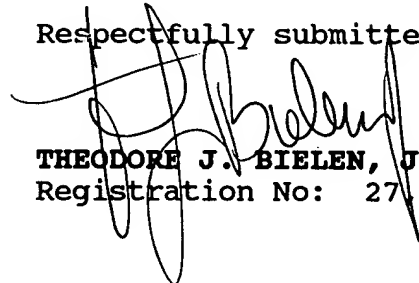
The Chin and Lau references show the use of nylon as a stent for reinforcing umbilical derived tissues. However, Lau and Chin add nothing to the combination of the Pratt references and Dardik et al to Applicant's claimed invention which calls for an allograft which is lyophilized without chemical denaturing.

The Dardik and Pratt references at best constitute an invitation to explore. However, this would not render an invention obvious under the Ex Parte Obukowicz decision, (27 USPQ 2d, 1063 (B.P.A.I. 1992)). Consequently, it is believed that Applicant's invention is not obvious from the references cited taken alone or in

combination. It is requested that the application be passed to publication at an early date.

A one-month extension of time is requested to respond to the Examiner's action of 24 September 2001. A check for the requisite fee is enclosed. Any deficiency or overpayment should be charged or credited to deposit account #02-2273.

Respectfully submitted,



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